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10/510,368	10/19/2004	Philippe Lefere	048777/283575	8789

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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,368	LEFERE ET AL.	
	Examiner	Art Unit	
	KATHERINE L. FERNANDEZ	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,12-15,17-19,21 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,4-7,12-15, 17-19, 21,23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/23/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. (US Patent No. 6,331,116) in view of Illig et al. (US Patent No. 5,352,434).

Kaufman et al. disclose a method of preparing an individual for a predetermined activity, wherein said predetermined activity requires the tagging of at least some colonic residue in the individual's digestive tract, said system comprising: a) administering less than 7 doses of a tagging agent in an aqueous suspension over a 20 to 36 hour administration period (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three 250 cc doses (i.e. less than 7 doses) of Barium Sulfate (i.e. tagging agent) suspension during the day (i.e. 24 hour administration period)); wherein each dose of tagging agent comprises greater than 2% w/v tagging agent (column 16, lines 43-49, referring to Barium Sulfate suspension of 2.1% w/v). Kaufman further disclose that fluid intake is preferably increased during the day, noting that cranberry juice is known to provide increased bowel fluids, but water could also be ingested (column 16, lines 49-54). Although Kaufman et al. do not specifically disclose that about 1 to 4 liters of total fluid are administered over the 20 to 36 hour administration period, it is well known that the recommended daily consumption

of water is about 8 cups a day (~2 liters). Therefore, by disclosing that fluid intake is increased during the day (i.e. during the administration period), Kaufman et al. disclose that more than 2 liters should be administered, which would fall within the limitation of administering 1 to 4 liters of total fluid over the administration period. Kaufman et al. further disclose that the patient is free from administration of laxatives or cathartic for at least 24 hours (column 16, lines 64-67). However, even if Kaufman et al. do not disclose the particular volume of fluid that is administered over the 20 to 36 hour administration period, they do teach increasing fluid intake, as mentioned above. It would have been obvious to one of ordinary skill in the art to have included in the method of Kaufman et al. the step of administering 1 to 4 liters of total fluid over the administration period, since Kaufman et al. teaches increasing fluid intake and it has generally been held to be within the skill level of the art to perform routine experimentation to determine appropriate parameters for implementing an invention, in particular to determine the sufficient amount of fluid intake needed to provide increased bowel fluids. With regards to claim 2, Kaufman et al. disclose the administration of tagging agent is less than 5 doses; the volume of each dose ranging between 25 to 250 ml (column 16, lines 43-49, referring to ingesting three 250 cc doses of Barium Sulfate); and wherein the total fluid intake is 1 to 3 liters over the 20 to 36 hour administration period (see above).

However, Kaufman et al. do not specifically disclose that each dose of tagging agent comprises about 10% to 80% w/v tagging agent. With regards to claim 4, Kaufman et al. disclose the administration of tagging agent is 3 doses (column 16, lines

43-49, referring to an exemplary bowel preparation operation including ingesting three doses of Barium Sulfate suspension). However, they do not disclose that the volume of each dose is about 20 ml and comprises about 40% w/v tagging agent.

Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt. They further disclose that the dosages of the contrast agent will vary according to the nature of ingredients used, but should be kept as low as consistent with achieving contrast enhanced imaging (3 doses of a volume of 20 mL can be considered low) (column 9, lines 28-47). They also disclose that the most preferred concentration is from about 15% w/w to about 40% w/w. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. to have the volume of each dose be about 20 mL and comprises about 10% to 80% w/v tagging agent, or specifically 40% w/v tagging agent, as taught by Illig et al, since it would have been obvious to try a low dosage (such as 20 mL) in order to reduce the toxicity potential, and a 40% concentration of the contrast agent falls within the preferred range of 15% to about 40% w/v, and therefore a 40% concentration would be expected to provide efficient and effective contrast/tagging (column 9, lines 28-46).

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Illig et al. as applied to claims 1-2 and 4-5 above, and further in view of

Bircher et al. ("Controlled Clinical Trial of Barium Sulfate Suspensions for Upper Gastrointestinal X-ray Examinations", 1971).

As discussed above, Kaufman et al. in view of Illig et al. meet the limitations of claim 1. However, they do not specifically disclose that the tagging agent is combined with Sorbitol or Mannitol. Bircher et al. disclose a study consisting of a double-blind clinical trial comparing two commercially available barium sulfate suspensions, several additives and methods used to alter the viscosity of the suspension (pg. 38, see Summary). They disclose that one of the barium sulfate suspensions included sorbitol, wherein the addition of sorbitol was able to significantly accelerate small intestinal transit (pg. 38, Section: Materials and Methods; pg. 42, Section: 4. Assessment of additives). They further disclose that some radiologists consider sorbitol added to barium sulfate suspensions improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Kaufman et al. to have the tagging agent (i.e. barium sulfate) be combined with sorbitol, as taught by Bircher et al., as the addition of sorbitol to tagging agents improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph).

4. Claims 7, 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. (US Patent No. 5,782,762) in view of The Children's Hopsital at Westmead Fact Sheet: Low Residue Diet, from now on referred to as CHW (Internet, August 2000,

http://web.archive.org/web/20010713061634/http://www.chw.edu.au/parents/factsheets/folowres.htm), and further in view of Bircher et al.

Vining et al. disclose a method and system for generating and displaying interactive, three-dimensional structures, such as the colon (column 5, lines 24-34). The method for imaging the colon includes the initial step of cleansing the colon (column 8, lines 1-4). As an alternative to cleansing the colon, the patient can be fed a low residue diet combined with a contrast agent (i.e. a tagging marker of the colonic residue), such as Barium Sulfate, for about 3 days (column 8, lines 12-20).

However, they do not specifically disclose that this low-residue diet would consist of food items that collectively comprise from about 600 to about 2,000 calories, from about 0.5 grams to about 10 grams of dietary fiber, from about 0.5% to about 20% of the calories derived from fat and from about 10% to about 30% by weight of solid material. They also do not specifically disclose that the food items include at least one solid food item selected from the group consisting of soup products, starch foods, grain foods, protein supplements, and fruit or vegetable foods, and at least one nutritional drink. Further, they do not specifically disclose that the one or more food items constitute a first feeding, a second feeding, and a third feeding. Also, they do not disclose that the tagging agent is combined with Sorbitol or Mannitol.

CHW disclose a low residue diet to reduce both the number and size of stools (pg.1, lines 8-9). They disclose that foods that are allowed each day for the diet include foods such as white pasta, white rice, meat, avocado, butter, and pumpkin, as well as milk, which can be considered as a nutritional drink (Table: Foods allowed each day).

The listed allowed foods fall into the groups listed above. Further, the diet should have 7-10 g of dietary fiber per day (pg.1, line 7). Selection from the foods listed would meet the above limitations (i.e. comprising from about 600 to about 2,000 calories, from about 0.5% to about 20% of the calories are derived from fat and about 10% to about 30% by weight of solid material). With regards to claim 25, CHW disclose a typical daily intake, which consists of breakfast, lunch, and dinner (i.e. first feeding, second feeding, third feeding) (pg. 2). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. to have the low residue diet meet the above limitations concerning the food items, as taught by CHW, since doing so would reduce both the number and size of stools, as taught by CHW (pg 1. lines 8-9). However, Vining et al. in view of CHW do not disclose that the tagging agent is combined with Sorbitol or Mannitol.

Bircher et al. disclose a study consisting of a double-blind clinical trial comparing two commercially available barium sulfate suspensions, several additives and methods used to alter the viscosity of the suspension (pg. 38, see Summary). They disclose that one of the barium sulfate suspensions included sorbitol, wherein the addition of sorbitol was able to significantly accelerate small intestinal transit (pg. 38, Section: Materials and Methods; pg. 42, Section: 4. Assessment of additives). They further disclose that some radiologists consider the addition of sorbitol to barium sulfate suspensions improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Kaufman et al. to have the tagging agent (i.e. barium sulfate) be

combined with sorbitol, as taught by Bircher et al., as the addition of sorbitol to tagging agents improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph).

With regards to claim 12, as discussed above, Vining et al. in view of CHW and Bircher et al. meet the limitations of claim 7. Although they do not specifically disclose that the total fluid intake by the individual is about 1-2 liters, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, an individual should be taking in a total fluid intake of about 1 to 2 liters.

5. Claims 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. ("MR Colonography Without Colonic Cleansing: A New Strategy to Improve Patient Acceptance", October 2001) in view of Callstrom et al. ("CT Colonography without Cathartic Preparation: Feasibility Study", June 2001) and further in view of Illig et al..

With regards to claim 13, Lauenstein et al. disclose a method for generating radiography images of one or more sections of an individual's gastrointestinal tract for screening, comprising (i) administering to the individual a low residue diet over a 36 hour period (pg. 824, left column, 2nd paragraph, referring to four principal low-fiber meals); (ii) administering to the individual one or more doses of a tagging agent over the 36 hour period, the tagging agent being an aqueous suspension at a volume of at least about 20 mL (pg.824, left column, 2nd paragraph, referring to 200 mL of a barium sulfate containing contrast agent); (iii) with the patient free from administration of laxatives or cathartics for at least 24 hours, imaging one or more sections of the individual's

gastrointestinal tract after the administration period (pg. 823, OBJECTIVE, referring to development of a strategy obviating colonic cleansing by performing MR colonography in conjunction with fecal tagging; pg. 824, Subjects and Methods); (iv) producing a radiography image of the one or more sections of the individual's gastrointestinal tract; said image showing stool marked with the tagging agent (see Figure 2, MR image of an individual after fecal tagging, stool is marked with the tagging agent); (v) screening the radiography image to identify the presence of any abnormality in the gastrointestinal tract without removing and/or subtracting the marked stool from the images (See Figures 2 and 3; pg. 826, right column, 2nd paragraph, referring to identifying colonic carcinomas and polyps, also the marked stool is not removed and/or subtracted from the images). However, Lauenstein et al. do not disclose that the administration period is at least a 48-hour period. Further, they do not specifically disclose that the aqueous suspension comprises about 10% to 80% w/v tagging agent.

Callstrom et al. disclose a study evaluating the methods for contrast material labeling of stool in the unprepared colon for computed tomography (CT) colonography and to determine their sensitivity for polyp detection (pg. 693, PURPOSE); They disclose that two to seven doses of 225 mL of dilute contrast material were orally administered during 24 or 48 hours and transverse CT images were assessed for effectiveness of stool labeling (pg. 693, MATERIALS AND METHODS). They concluded that a 48 hour administration period for ingestion of the contrast material is optimal (pg. 698, left column, 2nd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al.

to have the administration period be at least a 48-hour period, as taught by Callstrom et al, as they have found 48 hours to be an optimal administration period for ingestion of the contrast material (pg. 698, left column, 2nd paragraph). However, they do not specifically disclose that the aqueous suspension comprises about 10% to about 80% w/v tagging agent.

Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt (column 3, lines 13-27). They further disclose that the dosages of the contrast agent will vary according to the nature of ingredients used, but should be kept as low as consistent with achieving contrast enhanced imaging (column 9, lines 28-34). They further disclose that the most preferred concentration is from about 15% w/v to about 40% w/v (the limitation of at least 30% w/v tagging agent falls in this range) (column 9, lines 48-52). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. in view of Callstrom et al. to have their aqueous suspension comprise about 10% to 80% w/v tagging agent, as taught by Illig et al., since a preferred range of concentration of tagging agent is 15% to about 40% w/v, which falls within the limitation of about 10% to 80%, is expected to provide efficient and effective contrast/tagging. (column 9, lines 28-46).

With regards to claim 14, as discussed above, the above combined references meet the limitations of claim 13. Further, Lauenstein et al. disclose that the images are produced in connection with a predetermined activity, including MR colonography of the individual's colon (pg. 823, OBJECTIVE).

With regards to claim 15, as discussed above, the above combined references meet the limitations of claim 13. Further Lauenstein et al. disclose that the administration of tagging agent is less than 5 doses and the volume of each dose is between 25 to 250 mL (pg. 824, left column, 2nd paragraph, referring to 200 mL of barium sulfate containing contrast agent was ingested with each of 4 principal low-fiber meals (i.e. 4 doses). Although they do not specifically disclose that the total fluid intake is 1 to 3 liters over a 20 to 36 hour administration period, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, it is inherent that an individual should be taking in a total fluid intake of about 1 to 2 liters, which is within the limitation of 1 to 3 liters.

With regards to claim 18, as discussed above, the above combined references meet the limitations of claim 13. Further, Lauenstein et al. disclose that the tagging agent is Barium Sulfate (pg. 824, left column, 2nd paragraph).

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. in view of Callstrom et al. and Illig et al. as applied to claim 13 above, and further in view Kaufman et al.

With regards to claim 17, as discussed above, the above combined references meet the limitations of claim 13. Further, Lauenstein et al. disclose that the

administration of tagging agent in one or more doses. Further, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify their method to have the volume of each dose be about 20 mL and comprise 40% w/v tagging agent, as taught by Illig et al, since it would have been obvious to try a low dosage (such as 20 mL) in order to reduce the toxicity potential, and a 40% concentration of the contrast agent falls within the preferred range of 15% to about 40% w/v, and therefore a 40% concentration would be expected to provide efficient and effective contrast/tagging (Illig et al., column 9, lines 28-46).

However, they do not specifically disclose the administration of tagging agent is 3 doses.

Kaufman et al. disclose the administration of tagging agent is 3 doses (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three doses of Barium Sulfate suspension). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of the above combined references to have the administration of tagging agent be 3 doses, as taught by Kaufman et al., since 3 doses has been previously shown to be successful in tagging stool and therefore it would have been obvious to try 3 doses (column 16, lines 43-49).

7. Claims 19, 21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al.

Lauenstein et al. disclose a method of preparing an individual for a predetermined activity; wherein said predetermined activity requires the tagging of at

least some colonic residue in the individual's digestive tract; said method comprising the steps of (i) administering one or more food items having sufficient tagging agent incorporated therein so that consumption of the one or more food items by the individual causes the stool to become tagged (pg. 249, middle column, 2nd paragraph; pg. 252, middle column, 3rd paragraph, referring to administering barium already mixed into prepackaged meals). They further disclose that one or more food items are administered over at least a 24-hour period before the predetermined activity (pg. 249, middle column, 2nd paragraph, referring to meals given 36 hours before MR colonography). Lauenstein et al. further disclose that each of the one or more food items comprises at from about 0.01 g to about 150 g of tagging agent, which is equivalent to from about 10 mg to about 150,000 mg of tagging agent (pg. 249, middle column, 2nd paragraph, referring to 1 mg/mL barium sulfate administered in a dose of 200 mL (i.e. 200 mg of barium sulfate) with each of the 4 principal meals, which falls within the limitation of 10 mg to 150,000 mg of tagging agent). Although Lauenstein et al. do not specifically disclose that the individual's total fluid intake during the 24 hour administration period is 1 to 3 liters, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, it is inherent that an individual should be taking in a total fluid intake of about 1 to 2 liters, which is within the limitation of 1 to 3 liters. With regards to claim 24, Lauenstein et al. disclose that the predetermined activity is barium enema (pg. 249, left column, 3rd paragraph).

Although Lauenstein et al. do not specifically disclose that the total amount of tagging agent consumed by the individual during the at least 24 hour administration

period is at least 1g, Lauenstein et al. do disclose that 0.8 g. of the tagging agent is consumed during the at least 24 hour administration period (pg. 249, middle column, 2nd paragraph, referring to 1 mg/mL barium sulfate administered in a dose of 200 mL (i.e. 200 mg of barium sulfate) with each of the 4 principal meals, which is 0.8 g consumed during the at least 24 hour administration period). It would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to have the total amount of tagging agent consumed by the individual during the at least 24 hour administration period be at least 1g, as it has generally been held to be within the skill level of the art to perform routine experimentation to determine appropriate parameters for implementing an invention, in particular to determine the sufficient dosage to tag stool.

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. as applied to claim 19 above, and further in view of Bircher et al.

As discussed above, Lauenstein et al. meet the limitations of claim 19. However, they do not specifically disclose that their method further comprises the step of providing a mild laxative regimen prior to the predetermined activity. Bircher et al. disclose a study consisting of a double-blind clinical trial comparing two commercially available barium sulfate suspensions, several additives and methods used to alter the viscosity of the suspension (pg. 38, see Summary). They disclose that one of the barium sulfate suspensions included sorbitol wherein the addition of sorbitol was able to significantly accelerate small intestinal transit (pg. 38, Section: Materials and Methods; pg. 42, Section: 4. Assessment of additives). They further disclose that some

radiologists consider sorbitol, which is a well known mild laxative, added to barium sulfate suspensions improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Lauenstein to further comprise the step of providing a mild laxative regimen prior to the predetermined activity, as taught by Bircher et al., as the addition of sorbitol, a well known mild laxative, to tagging agents improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph; pg. 42, Section: 4. Assessment of additives).

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. as applied to claim 19 above, and further in view of Callstrom et al.

As discussed above, Lauenstein et al. meet the limitations of claim 19. However, they do not specifically disclose that the last dose is administered to the individual more than 8 hours prior to the predetermined activity. Callstrom et al. disclose a study evaluating the methods for contrast material labeling of stool in the unprepared colon for computed tomography (CT) colonography and to determine their sensitivity for polyp detection (pg. 693, PURPOSE); They disclose that two to seven doses of 225 mL of dilute contrast material were orally administered during 24 or 48 hours and transverse CT images were assessed for effectiveness of stool labeling (pg. 693, MATERIALS AND METHODS). They disclose that for a 48 hour, 4 dose group, with the last dose administered 12 hours prior to the CT colonography (pg. 694, middle column, 2nd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to have the last dose

administered to the individual more than 8 hours prior to the predetermined activity, as taught by Callstrom et al., as this has been shown to provide the best specificity (see pg. 696, Table: Results of Contrast Material Labeling of Stool at CT Colonography).

Response to Arguments

10. Applicant's arguments filed on June 17, 2008 have been fully considered but they are not persuasive.

With regards to the Illig reference, the applicant argues that a skilled person would not be motivated to administer three doses of tagging agent each having a specific volume of 20 mL and a specific concentration of 40% w/v as Illig et al. teach that a "low dose" is some concentration at a volume of 10 mL. Applicant relies on the examples given by Illig et al. which disclose formulations having a 10 mL total volume. However, these are solely examples and Illig et al. disclose that the dosages of the contrast agent used according to the method of their invention will vary (column 9, lines 28-32; also see column 4, lines 35-47). Further, as discussed in the previous Office Action, Illig et al. disclose that the dosage should be kept as low as is consistent with achieving contrast enhanced imaging in order to minimize toxicity potential (column 9, lines 30-34). Compared to tagging agent dosages consisting of volumes of 200 mL-250 mL as disclosed by the prior art (i.e. Kaufman et al., Lauenstein et al.), a volume of 20 mL can still be considered to be a "low volume", and therefore it would have been within the skill of one of ordinary skill in the art to administer tagging agent doses consisting of a low volume, such as 20 mL, as taught by Illig et al., in order to minimize toxicity potential. Applicant further argues that the Illig reference is not combinable with the

Lauenstein, Callstrom, or Kaufman references, as Illig et al. disclose the use of very low volumes and the other references teach volumes that are some 200 times greater than the Illig et al. formulations. However, although the concentration and volume of the dosages differ amongst the above references, they all provide and require efficient and effective contrast in the diagnostic images, and therefore it would be within the skill of one of ordinary skill in the art to substitute or modify the dosages according to the Illig reference as the above references (i.e. Lauenstein, Callstrom, Kaufman) require effective contrast in diagnostic images and the dosages taught by Illig provide effective contrast.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768